January 13, 2022

Irvine Scientific Sales Co., Inc.
Jayme Yamaguchi-Owens
Senior Manager Regulatory Affairs
2511 Daimler Street
Santa Ana, CA 92705

Re: K171224
Trade/Device Name: Arctic™ Sperm Cryopreservation Medium
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL

Dear Jayme Yamaguchi-Owens:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 31, 2017. Specifically, FDA is updating this SE Letter to include the correct version of the 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Monica Garcia, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-2791, monica.garcia@fda.hhs.gov.

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 31, 2017

Irvine Scientific Sales Co., Inc.
Jayme Yamaguchi-Owens
Senior Manager Regulatory Affairs
2511 Daimler Street
Santa Ana, CA 92705

Re: K171224
Trade/Device Name: Arctic™ Sperm Cryopreservation Medium
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 31, 2017
Received: August 1, 2017

Dear Jayme Yamaguchi-Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171224

Device Name
Arctic™ Sperm Cryopreservation Medium

Indications for Use *(Describe)*
Arctic™ Sperm Cryopreservation Medium is intended for use in assisted reproductive procedures involving the cryopreservation and storage of human sperm.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. General Information on Submitter

Submitter/Address: Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705
Telephone: 800-437-5706
Facsimile: 949-261-6522

Contact Person: Jayme Yamaguchi-Owens
Senior Manager Regulatory Affairs
Irvine Scientific
2511 Daimler Street
Santa Ana, CA 92705
Tel: 949-261-7800 ext. 254
Fax: 949-261-6522
Email: jfy@irvinesci.com

II. Date Prepared:

August 29, 2017

III. General Information

Device Name: Arctic™ Sperm Cryopreservation Medium

Common Name: Sperm Cryopreservation Medium

Classification Name: Reproductive Media and Supplements (21 CFR 884.6180)

Product Code: MQL (Media, Reproductive)

Regulatory Class: II

IV. Predicate Device:

Sperm Maintenance Medium with Glycerol (K991337) manufactured by Irvine Scientific Sales, Co., Inc. This predicate device has not been subject to any design related recalls.

V. Description of the Device:

The Arctic™ Sperm Cryopreservation Medium is a modified version of the predicate device (K991337). It is a defined medium consisting of salts, buffering materials, cryoprotectants, vitamins, amino acids, minerals, carbohydrates, surfactant, energy source, and human serum albumin.

The Arctic™ Sperm Cryopreservation Medium is a single-use device that is aseptically filled into sterilized vials and has a sterility assurance level (SAL) of 10^{-3}. This medium is supplied in a fill volume of 5 mL, and twelve (12) 5mL vials are included in a package. The product is tested for pH, osmolality, sperm cyrosurvival, endotoxin and sterility before lot release, and has a shelf-life of 18 months.

VI. Indications for Use

Arctic™ Sperm Cryopreservation Medium is intended for use in assisted reproductive procedures involving the cryopreservation and storage of human sperm.

VII. Comparison of Intended Use and Technological Characteristics with the Predicate Device

Device/Predicate Device	K171224 (subject device)	K991337 (predicate device)
Indications for Use	Arctic™ Sperm Cryopreservation Medium is intended for use in assisted reproductive procedures involving the cryopreservation and storage of human sperm.	Sperm Maintenance Medium with Glycerol is intended for use in assisted reproductive procedures involving the cryopreservation and storage of human sperm.
Appearance	Clear, free of particulate	Clear, light yellow, free of particulate
pH	Same as predicate	7.25-7.54
Osmolality	2300-2600 mOsm/kg	2362-2532 mOsm/kg
Formulation	21 Ingredients	20 Ingredients
The subject and predicate devices have the same indication – cryopreservation and storage of human sperm. The subject and predicate devices have the same or comparable appearance, pH, and osmolality. The only differences in formulation are the replacement of L-glutamine with L-alanyl glutamine, addition of MOPS buffer, and minor modifications in concentrations of certain ingredients in the subject device. The differences noted are minor and do not raise different questions of safety and effectiveness. In addition to pH and osmolality, the subject and predicate devices have the same acceptance criteria for the sperm cyrosurvival assay and sterility testing, and the subject device has a more stringent acceptance criterion for endotoxin testing (≤1.0 EU/ml vs. ≤3.0 EU/ml).		

VIII. Summary of Non-Clinical Performance Testing:

The following studies have been performed to support substantial equivalence to the predicate device:

- pH (7.25-7.54)
- Osmolality (2300-2600 mOsm/kg)
- Aseptic Processing Validation testing per ISO 13408-1:2008 and ISO 13408-2:2003
- Sterility testing (no microbiological growth) per USP <71>

- Endotoxin testing (≤1.0 EU/ml) per USP <85>
- Sperm Cryosurvival Assay

  Donor semen was mixed with the test medium and control (predicate device) and cryopreserved in liquid nitrogen. After thawing, sperm motility was determined at three time points: post thaw, post gradient separation, and two (2) hours post wash. Success of this test was based on ≥80% of control motility.

- Shelf-life testing (accelerated) was conducted to ensure that the following acceptance criteria for product characteristics are met at time zero and the end of shelf-life:
  - ✓ pH – 7.25-7.54
  - ✓ Osmolality – 2300-2600 mOsm/kg
  - ✓ Sperm Cryosurvival Assay – ≥80% of the control motility
  - ✓ Endotoxin – ≤1.00 EU/ml (LAL)
  - ✓ Sterility – No microbiological growth

XI. Conclusion:

The subject and predicate devices have the same intended use. Although there are differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.